

R E M A R K S

This is in response to the Office Action that was mailed on June 20, 2002. Claims 13 and 18 have been amended to specify that the delipidated egg yolk particles used in this invention are spray-dried and porous, as disclosed for instance in lines 8-16 on page 8 of the specification (see also claim 20). No new matter is introduced by this Amendment. Claims 13-23 remain in the application.

HAMAGUCHI + 3

Claims 13, 15-17, and 19 were rejected under 35 USC 103(a) as being unpatentable over Hamaguchi in view of Mitsuya, Yano, and Levin.

Applicants present herewith the DECLARATION UNDER 37 CFR 1.132 of Noriyuki ISHIHARA. The ISHIHARA Declaration establishes that the powder compositions of the present invention are markedly different from the egg-white powder compositions taught by Hamaguchi.

As summarized on page 9 of the ISHIHARA Declaration, Powder Compositions A and B, representative of the present invention, significantly suppressed undesired bitterness while comparable Egg-White Powder Compositions A and B, representative of the Hamaguchi disclosure, failed to suppress bitterness from the same source. Quantitatively, the prior art compositions showed a bitterness of 4.8 (close to strong bitterness) while the

compositions of this invention showed a bitterness of 1.2-1.8 (slight to little bitterness).

As summarized on page 10 of the ISHIHARA Declaration, Powder Compositions C and D, representative of the present invention, were significantly more stable on standing than were comparable Egg-White Powder Compositions C and D, representative of the Hamaguchi disclosure.

Quantitatively, the POV measured for Egg-White Powder Composition C reached 50 meq/kg after 30 days, while the comparable measurement for Powder Composition C after 30 days was only 0.5 meq/kg. Similarly, the POV (peroxide value) measured for Egg-White Powder Composition D (Hamaguchi) reached 60 meq/kg after 30 days, while the comparable measurement for Powder Composition D (the present invention) after 30 days was only 0.5 meq/kg.

The superior effects exhibited by the Powder Compositions representative of the present invention are neither taught nor suggested by the Hamaguchi disclosure, even in view of the ancillary references.

HAMAGUCHI + 4

Claims 14 and 18 were rejected under 35 USC 103(a) as being unpatentable over Hamaguchi in view of Mitsuya, Yano, Levin, and Ueda.

Regarding claim 14, it is respectfully urged that combining 5 references to reject a claim is tantamount to evidence that the invention is *prima facie unobvious*. The number of different references combined by the Examiner to reject the claims herein raises the question of whether the rejection as stated involves improper hindsight. The rigorous burden placed upon an Examiner for establishing a *prima facie* case of obviousness has recently been reviewed by the United States Court of Appeals for the Federal Circuit in *In re Lee*, 61 USPQ2d 1430, (Fed. Cir. 2002). In *Lee*, the court observes:

When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) (“the central question is whether there is reason to combine [the] references,” a question of fact drawing on the *Graham* factors).

... *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”); *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (“teachings of references can be combined only if there is some suggestion or incentive to do so.”) (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

The need for specificity pervades this authority. See, e.g., *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan,

with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references").

It is respectfully urged that the Examiner has not met that burden with respect to the rejection of record.

Regarding claim 18, the Examiner acknowledges that even though he has combined five (5) references to reject these claims, the prior art still does not teach "delipidated egg yolk particles having pores ranging in size from 0.1 to 10 μm ". The Examiner argues however that "any pore size would have been an obvious result effective variable" of air pressure and temperature parameters in the spray drying process for making the particles. Applicants respectfully controvert that argument. It is noted that the specification herein teaches, in lines 8-16 on page 8, that

One of the largest features of the present invention resides in that there is employed an operation of mixing the delipidated egg yolk with water, and spray-drying the resulting mixture. Since such an operation is employed in the present invention, the resulting delipidated egg yolk particles are porous, on which surfaces there can be surprisingly formed a large number of pores (pore size being from about 0.1 to 10

μm) which cannot be found in the conventional delipidated egg yolk particles.

Applicants respectfully request that the Examiner supply a sixth (6th) reference establishing that pores ranging in size from 0.1 to 10 μm can be imparted to delipidated egg yolk particles by adjusting air pressure and temperature parameters.

MITSUYA

Claims 13-19 were rejected under 35 USC 103(a) as being unpatentable over Mitsuya in view of Levin, Yano, Ueda, and Hamaguchi. Claims 20-23 were rejected under 35 USC 103(a) as being unpatentable over Mitsuya in view of Ueda, Yano, Hamaguchi, Likuski, Broderick, Maloney, and Meusel. Each of these rejections is respectfully traversed.

Mitsuya provides a generic disclosure of preparing a delipidated egg yolk powder by means of spray-drying (although this is not supported by examples). However, as to the mixing with a fat or oil such as fish oil, Mitsuya teaches that:

... the mixing as referred to herein may be simply a step of homogeneous stirring with Super-Mixer or the like, without necessitating dispersing with water or the like or spray-drying.

Mitsuya is completely silent as to the method of stirring into a homogeneous mixture under reduced pressure as taught by the present invention.

This stirring in feature is a crucial distinction over Mitsuya. Properties such as flowability and flavor of the resulting powder composition are completely different in accordance with the different mixing procedures employed in the preparation of the powder. This is clearly established by the Declaration under 37 CFR 1.132 of Senji SAKANAKA that was submitted on June 14, 2001.

In the SAKANAKA Declaration, the first step of the process for preparing the powder composition is a vacuum drying method, which corresponds to Mitsuya Example 1. The delipidated egg yolk particles (B) are prepared by a spray-drying method. This corresponds to the present invention (and to generic disclosure of Mitsuya).

Four different powder compositions – AS, BS, AR, BR – are prepared by a second step. AS and BS are embodiments in which a mixture of the delipidated egg yolk particles (A) or (B) with a fish oil are stirred by using a Super Mixer into a homogeneous state. These embodiments of the second step correspond to Mitsuya Example 2, in which a Super Mixer is used. In contrast, AR and BR are embodiments in which a mixture of the delipidated egg yolk particles (A) or (B) with a fish oil are dried under reduced pressure. These embodiments correspond to the method of the present invention.

It should be noted that even if the delipidated egg yolk particles (B) were prepared by spray-drying in accordance with the generic disclosure of Mitsuya,

Mitsuya does not teach that the delipidated egg yolk particles should be mixed with fish oil and dried under reduced pressure. Therefore, AS corresponds to Examples 1 and 2 of Mitsuya, and BS corresponds to the general disclosure of Mitsuya and Example 2 of Mitsuya.

In the course of an interview with Applicants' representative, Richard Gallagher, on December 4, 2001, the Examiner kindly agreed that the SAKANAKA Declaration does in fact compare prior art (Mitsuya) products to products made in accordance with the present invention. Applicants point out that the angle of repose and the fish odor in AS and BS ("prior art") are both notably poorer than corresponding parameters obtained by the method of the present invention (BR).

The ancillary references fail to make up the deficiencies of the primary reference. For instance, it is noted that while Ueda discloses a spray-dried egg yolk powder, he fails to disclose spray-dried, delipidated egg yolk particles. It goes without saying that Ueda does not disclose delipidated egg yolk particles having pores. While Yano discloses a spray-drying process, his spray-drying is carried out before the delipidation process. In contrast, in the present invention, the egg yolk is first delipidated and only then spray-dried. In the Broderick technology, sweetener is impregnated in pores for controlled release. In direct contrast thereto, the functional food material in the present invention consists of substances that are not to be **released** from pores. It is respectfully

submitted that the Levin, Yano, Ueda, Hamaguchi, Likuski, Broderick, Maloney, and Meusel references -- even when combined with Mitsuya -- fail to render the compositions or processes of the present invention obvious.

Conclusion

It is believed that a full and complete response has been made to the Office Action. Accordingly, the Examiner is respectfully requested to pass the application to Issue.

If there are any matters requiring discussion remaining in this application, the Examiner is invited to contact Mr. Richard Gallagher, Registration No. 28,781 at (703) 205-8008.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,
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Marked up claims showing amendments:

13. (twice amended) A powder composition[, characterized in that the powder composition] which comprises

spray-dried, porous delipidated egg yolk particles and a functional food material, which functional food material is selected from the group consisting of substances that have undesirable flavor and substances that are susceptible to deterioration,

wherein the functional food material [being] is impregnated in pores of the spray-dried, porous delipidated egg yolk particles, and wherein an angle of repose is 60° or less, as measured under the conditions of the water content of 5 ± 2%, relative humidity of 40%, and a temperature of 25°C.

18. (amended) The [powder] powder composition of claim 13, wherein said spray-dried, porous [the pore size of the] delipidated egg yolk particles [is] have pores ranging in size from 0.1 to 10 µm.